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UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of		
	John Jacob Vander Zanden, et al.	)Examiner
Serial No.	10/622,170	)Gehman, B.P.
Filed:	July 16, 2003	)Art Unit
For:	TITRATION/COMPLIANCE PACK	)3728

DECLARATION UNDER 37 C.F.R. 1.131

We, John Jacob Vander Zanden and Rodney Terwilliger, hereby declare:

That we are the Applicants of the hereinabove identified patent application and the inventors of the subject matter therein described and claimed;

That prior to March 6, 2003, we have conceived and reduced to practice, in the United States of America, the invention as defined in Claims 1-25 of the hereinabove referenced patent application as evidenced by the following:

1. Prior to March 6, 2003, we jointly prepared a disclosure of the invention describing the apparatus and method of the invention, a copy being attached hereto as Exhibit A, with dates prior to March 6, 2003 deleted.

2. The invention as defined in Claims 1-25 of the present application is described in Exhibit A.

3. Apparatus defined by Claims 1-25 for practicing the process of the present invention, was constructed and

operated prior to March 6, 2003. The apparatus is described in the description and table in Exhibit A.

We hereby declare that all statements made herein are of our own knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such false statements may jeopardize the validity of the subject patent application.

4 MARCH 05

John Jacob Vander Zanden (Date)

Rodeny Terwilliger (Date)

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS, PO BOX 1450 ALEXANDRIA, VIRGINIA 22313-1450, ON

June 8, 2005

6/8/05

(DATE SIGNED) WALTER A. HACKLER
REG. NO. 27, 792

ALLERGAN
Global Glaucoma Marketing

Record of Invention / Memantine Titration – Dose Packs

ROI No. [redacted]
Date: [redacted]
General Area of Research – Eyecare Pharmaceuticals

1) **Proposed Title of Invention**
Memantine Titration Pack

2) **General Description**
Idea is a titration and ongoing dosage pack for dosing of oral Memantine for the indication of preventing further nerve cell loss in glaucoma patients. To avoid adverse events associated with the drug, patients prescribed memantine therapy need to be titrated upwards from 5mg of memantine per day to maintenance doses of either 10 or 20mg per day.

Memantine approved for other indications requires the same titration schedule to avoid drug-related adverse events. Currently two products are marketed in Europe for the indication of Alzheimer's Dementia. Both products, Axura (Merz) and Ebixa (Lundbeck), are marketed in packages of 5 blister sheets of 10 each 10mg tablets.

The titration schedule to reach a maintenance dose is as follows:

DOSAGE REGIMEN	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Tablets to Dosage
Week One	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg	½
Week Two	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg	5 mg	1
Week Three	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg	1
Week Four	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg	10 mg	1
Week Five	15 mg	15 mg	15 mg	15 mg	15 mg	15 mg	15 mg	1½
Week Six	15 mg	15 mg	15 mg	15 mg	15 mg	15 mg	15 mg	1
Week Seven	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	2
Week Eight	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	20 mg	2

Referring to the table above, it is clear that with the currently marketed packages, the patient is required to somehow track where they are in the titration schedule and take ½ tablet, 1 tablet, 1 ½ tablets or 2 tablets. Because the typical patient requiring this medication is in an age range over 50 years and has been prescribed the medication to slow the progression of blindness it is likely that this manipulation of the tablets, and tracking of the titration schedule will be problematic. Considering that the very nature of a titration schedule is to prevent adverse events as a result of mis-dosing, it is safe to assume that a package which removes these patient requirements would be safer and more beneficial to the patient's therapy.

The proposed titration pack from Allergan would be set up in weeks with the exact strength of tablet set in an individual blister pack that would be labelled for a specific day. This means that the only patient manipulation required would be to adhere a sticker starting with the day of the week in which the patient begins dosing.

3) **Person Corroborating Invention**
Hans-Peter Pfleger

4) **Inventors**
Jacob Vander Zanden, Rodney Terwilliger

5) **Approval for Submission**
Hans-Peter Pfleger – Department Head

Exhibit A

4. **PERSONS CORROBORATING INVENTION:**

Rodney Terwilliger

5. **INVENTOR(S):** (If not a United States citizen, note country)

1) *First Name*	*Middle Initial*	*Last*	*Date*
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Signature:			

3) *First Name*	*Middle Initial*	*Last*	*Date*
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Signature:			

4) *First Name*	*Middle Initial*	*Last*	*Date*
Street Address	*City*	*State and Zip Code*	*Country of Citizenship*
Signature:			

APPROVAL FOR SUBMISSION
(read and understood)

By: _____
Department Head
(Full Name)

Date: [redacted]

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Exhibit A